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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/988,488	11/20/2001	Yasuhiro Sando	15162/04050	8768

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EXAMINER	
SNAY, JEFFREY R	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 03/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/988,488	SANDO ET AL.	
	Examiner	Art Unit	
	Jeffrey R. Snay	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 December 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-18,20-27,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 2, 4-18, 20-27, 50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12-28-05 has been entered.

General claim construction & interpretation

1. The preamble to each of claims 1, 2, 4-18, 20-27 and 46-51 makes reference to a "microchip." However, the body of each claim sets forth sufficient structure to fully define the claimed device. Further, the body of each claim fails to recite any limitation that refers back to the "microchip" referenced in the preamble. Finally, the specification fails to provide any definition for the preamble term "microchip." Instead, the specification teaches only that the claimed "microchip" is a device which is fabricated according to the structural limitations now recited in the claims. See e.g. paragraphs [0009 - 0019]. Accordingly, the term "microchip" presently recited in the preamble to claims 1-27 is interpreted as adding nothing more to the limitations of the claims beyond that which would be added by the term "device" or "apparatus."

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 1, 2 and 4-8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('807) in view of Knapp et al ('471).

Referring to Figure 3 of Liu, the prior art device includes a flow pass (10) for containing a reaction to be analyzed. The flow pass extends from entry point (12) to exit point (13). A detection target region is provided within a portion of the flow pass, and is formed in the device depicted in Figure 3 as the horizontal section of the flow pass. A fiber optic cable (22) is connected to the flow pass at the proximal end of the detection target region, and is used to introduce excitation illumination from a light source. A detector (24) is positioned orthogonal to the detection target region to collect that light which is emitted in response to the excitation illumination of the reaction. The optical path, necessitated by the structural orientation depicted in Figure 3, thus originates at the left-most end of the horizontal detection target region, extends in a longitudinal extension direction of the flow pass through the detection target region to at least the right-most end of the horizontal detection target region, and further extends orthogonal to the detection target region toward the detector. The device of Liu further includes a reflective mirror positioned opposite the detector such that emitted light traveling in a direction away from the detector is thereby redirected back toward the detector.

An annotated copy of Figure 3 from Liu is produced below.

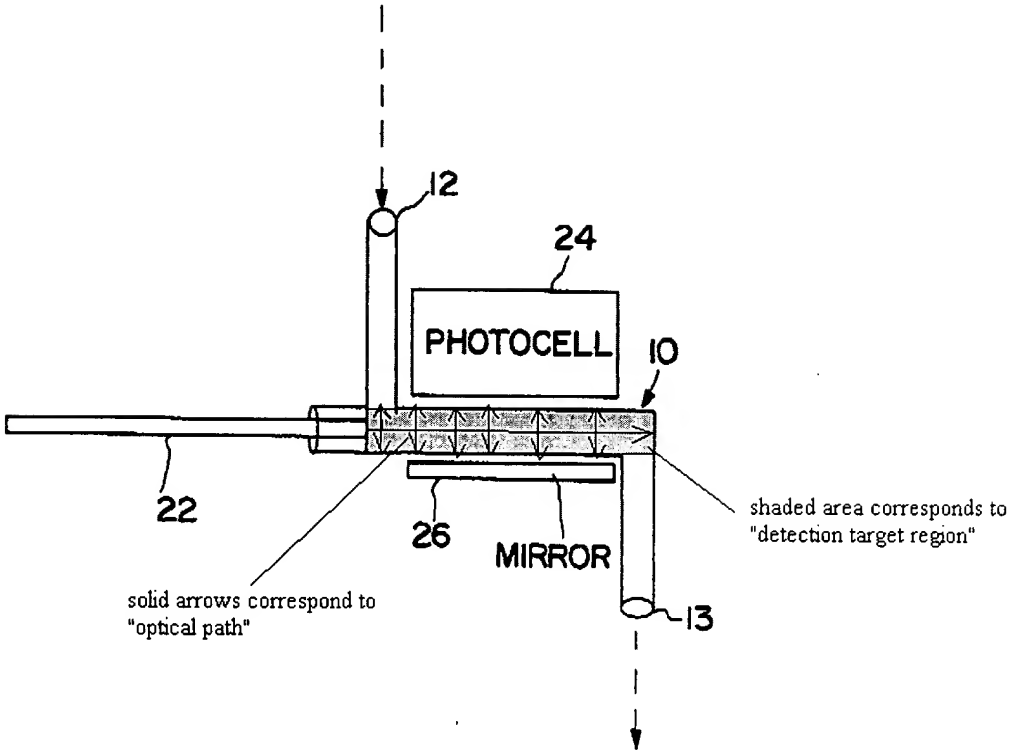

FIG. 3
annotated by the Examiner on 02042005

Liu specifically teach that the flow pass is provided such that its length is significantly greater than both its width and depth. See e.g. Liu at column 5, penultimate paragraph, suggesting use of a tubular flow path having dimensions of 0.3 mm inner diameter and length corresponding to the detection target region of 212 mm.

With respect to instant claim 4, the annotated figure above clearly indicates that the detection target region (shaded) is larger than the detection area (corresponding to the dimension of the detector).

The outlet port (13) in Liu would have constituted the presently recited "ventilator port."

The device of Liu differs from the presently claimed invention in that Liu discloses only a single flow path inlet, rather than a plurality of branched flow lines controlled by pumps, including a confluence of such flow lines located proximate to an end of the detection target region. However, Knapp et al disclose a flow-through optical analysis device in which various fluids are conducted to the sensing area via branched flow paths, valves and micropumps. See particularly Figure 4A of Knapp et al. It would have been obvious to one of ordinary skill in the art to modify the sensor of Liu to further include multiple branched flow inlets, and corresponding flow controls such as valves and micropumps, in order to enable introduction of multiple sample fluid flows either simultaneously or consecutively, as per the teaching of Knapp et al. The positioning of such confluence proximate to the detection region would have been necessary in order to enable the desired optical inspection of the mixed reagent streams, as per the teaching of Knapp et al.

6. Claims 1, 2, 4-18, 20 and 22- 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('207) in view of Knapp et al ('471).

Referring to Figure 4 of Liu, the prior art device includes a flow pass (10) which further constitutes a detection target region. Specifically, sample reaction fluid is caused to flow through the flow pass, where it interacts with an internally coated reagent. The reacted sample is subjected to excitation light, and fluorescence emission

generated in the detection target area is collected and analyzed. In this manner, the flow cell in Liu constitutes a detection target region.

The device of Liu further comprises an optical fiber at a proximal end of the flow pass, coupled to a laser light source, for introduction of excitation light to the detection target area. An optical path is thus provided along the entire length of the detection target area, and is oriented in an extension direction of the flow pass, as presently recited in claim 6. The length of the optical path is greater than the depth and width (i.e. diameter) of the flow pass as indicated by Liu at column 6, line 30. The optical path is optionally doubled by provision of a mirrored surface at the distal end of the flow pass (column 5, lines 42-44).

With respect to instant claims 12 and 27, Liu discloses the presence of a reagent fixing unit in the flow pass. Specifically, Liu teaches the provision of indicator molecules (24), optically responsive to an analyte of interest, being coated on an interior surface of the flow pass.

The device of Liu further comprises a detector (38), receiving emitted light via the same optical fiber through which excitation light is introduced. Emitted light from the sample reaction is passed back through the detection target area to the proximal end of the optical fiber positioned outside the flow pass. This proximal end of the optical fiber in Liu corresponds to the "light detection area" presently recited in claim 4. Thus, the detection target region in Liu is larger than the light detection area. Further, the optical fiber constitutes a light guide for conducting light from the detection target region to the light detection area, as presently recited in claims 13 and 14.

With respect to instant claims 15 and 16, reciting optical waveguides at each end of the detection target region, it is noted that this structure is clearly depicted in Liu's alternative embodiment shown in Figure 3.

Regarding instant claim 17, see Liu at column 5, lines 42-44 disclosing the provision of a mirror at one end of the detection target area, such that the length of the optical path is doubled. Alternatively, and with respect to instant claims 19 and 20, Liu teaches the entire inner surface of the LWCC being reflective of the excitation light (see column 3, lines 10-13).

With respect to instant claims 22 and 23, see Figure 4 of Liu depicting a lens for condensing and collecting emitted light, and guiding the collected light to a detector.

The outlet port in Liu would have constituted the presently recited "ventilator port."

The device of Liu differs from the presently claimed invention in that Liu discloses only a single flow path inlet, rather than a plurality of branched flow lines controlled by pumps, including a confluence of such flow lines located proximate to an end of the detection target region. However, Knapp et al disclose a flow-through optical analysis device in which various fluids are conducted to the sensing area via branched flow paths, valves and micropumps. See particularly Figure 4A of Knapp et al. It would have been obvious to one of ordinary skill in the art to modify the sensor of Liu to further include multiple branched flow inlets, and corresponding flow controls such as valves and micropumps, in order to enable introduction of multiple sample fluid flows either simultaneously or consecutively, as per the teaching of Knapp et al. The positioning of

such confluence proximate to the detection region would have been necessary in order to enable the desired optical inspection of the mixed reagent streams, as per the teaching of Knapp et al.

7. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('207) in view of Knapp et al, as described above, and further in view of Chen ('453).

The device of Liu, as modified above in view of Knapp et al, differs from the presently claimed invention in that Liu fails to specify the mirrored surface being formed of a metallic film. However, the provision of metallic films as mirrors for guiding light in an optical sensor were notoriously well known in the art, and would have been obvious to one of ordinary skill in the art to accomplish the specific purpose taught by Liu. Chen discloses one such application of a silver mirror at the distal tip of a fiber optic sensor. See Figure 2d of Chen.

8. Claims 50 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Liu ('207) in view of Knapp et al ('471), as applied to claim 17 above, and further in view of either one of Neuschafer et al and Burgess, Jr. et al.

The device of Liu, as modified above in view of Knapp et al, differs from the claimed invention in that light is directed into and out of the flow channel via end portions, rather than top and bottome portions thereof. However, it was well known in the art of optical sensors to provide any desired optical components in order to direct light to and from sensor regions at any desired locations and orientations. For example,

each of Neuschafer et al and Burgess, Jr. et al disclose optical waveguide sensors in which grating elements are provided in order to enable incident and emitted light to be guided from a sensing flow channel at orthogonal angles with respect to the flow channel. It would have been obvious to one of ordinary skill in the art to similarly modify the device of Liu to enable incident and emitted light to be guided from above and/or below a horizontally oriented flow channel in order to render the sensitive region of the device more accessible to optical components, such as light sources and detectors, as per the teaching of either one of Neuschafer et al and Burgess, Jr. et al.

Response to Arguments

9. Applicant's arguments filed 12-28-05 have been fully considered but they are not persuasive. Applicant argues that the prior art either (i) fails to teach a confluence in which, for example, specimen and reagent flow can be joined or (ii) fails to teach the ventilator port being proximate the detection region. The arguments are not persuasive because, first, the instant claims do not require any structural definition regarding the claimed "confluence." Second, the ventilator ports depicted in the prior are extend to the detection region.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey R. Snay whose telephone number is (571) 272-1264. The examiner can normally be reached on Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jeffrey R. Snay
Primary Examiner
Art Unit 1743

jrs